Pharmaceutical Material Compliance Statement from Blue Line

Material Compliance & Surface Integrity
To ensure maximum hygiene and chemical resistance in Grade A/B environments, Blue Line A/S utilizes a selection of high-performance materials rigorously tested for pharmaceutical use.

Pharmaceutical properties and suitability of stainless Steel AISI 316L (EN 1.4404)
The chassis of our HMIs and Mobile Operator Stations are constructed from AISI 316L stainless steel, which is the industry standard for sterile environments.

- Corrosion Resistance: The high molybdenum content in 316L provides superior resistance to chlorides and aggressive disinfectants compared to 304 steel.
- Surface Finish: Surfaces are processed to a low roughness, minimizing the risk of microbial adhesion and ensuring compliance with EU GMP Annex 1 regarding easy-to-clean surfaces.
- FDA & ISO: Meets FDA requirements for non-reactive, non-absorptive contact surfaces that do not shed particles (ISO 14644 compliance).

Pharmaceutical properties and suitability of PEEK (Polyether Ether Ketone)

The chassis of our cleanroom tablets for cleanroom grades A, B, C, and D (corresponding to ISO 5 to ISO 8) is made of PEEK which is a high-performance thermoplastic widely used in pharmaceutical and medical applications due to its excellent material properties.

Key pharmaceutical properties:

- Chemical resistance: Highly resistant to a broad range of chemicals, including acids, bases, and organic solvents, making it suitable for aggressive pharmaceutical environments.
- Biocompatibility: PEEK is biocompatible and meets many regulatory standards (e.g., ISO 10993), allowing safe contact with biological systems.
- Thermal stability: It withstands high temperatures (continuous use up to ~250 °C), enabling repeated sterilization as described.
- Low extractables and leachables: Minimizes contamination risk in drug manufacturing processes.

Updated 24.03.2026

- Mechanical strength: High strength and stiffness with good wear resistance, ensuring durability in demanding applications.

Suitability in pharmaceutical use:

- Ideal for equipment components due to its robustness and chemical inertness.
- Suitable for cleanroom environments because it generates low particulates.
- It can be used in medical devices and implants due to biocompatibility and stability.
- Compatible with common sterilization methods such as Spor-Klenz, HP/VHP, steam, gamma radiation, ethylene oxide and others.

Overall, PEEK is highly suitable for pharmaceutical applications where purity, durability, and resistance to harsh conditions are critical.